

Do you have any thoughts concerning the verbiage that companies are using for their SPL Principal Display Panel and Alternate Image Text? A lot? A little?

The pop-up text (below in the screenshot) is the alternate image text that comes up when the cursor is posed over the item shown in the principal display panel. It looks like the companies are now putting a lot of text in each one of the alternate image text boxes.

Please use the screenshots to describe this agenda item better, if it is accepted for the agenda.

Lonnie Smith told us in the 30-minute recent training "SPL Content of Labeling Data Elements", that the alternate image text is used for non-image devices when they look at the label (Section 508 Federal government websites and computer screen readers for the visually impaired).

The first example below uses a huge amount of text in the alternate image label and in the label itself. The second example below uses a very minimal amount in the alternate image label and a moderate amount in the label itself.

#### Example for Neulasta:

Principal Display Panel

NDC 55513-192-01

1 - Single Use Neulasta Prefilled Syringe

1 - Sterile On-body Injector for Neulasta

AMGEN®

Neulasta® Onpro™ kit

(pegfilgrastim)

Pegylated Recombinant Methionyl Human Granulocyte Colony-Stimulating Factor

(PEG-r-metHuG-CSF) derived from E Coli

6 mg/0.6 mL\*

6 mg/0.6 mL\*

\*Prefilled syringe contains 0.64 mL to deliver 6 mg/0.6 mL when used with on-body injector

For Subcutaneous Use Only

Carton Contents (intended to be dispensed as a unit):

- 1 sterile On-body Injector for Neulasta
- 1 Neulasta prefilled syringe labeled for use with on-body injector only
- 1 patient instructions for use
- 1 healthcare provider instructions for use, 1 package insert
- 1 reference guide

This Product Contains Dry Natural Rubber

Store at 2° to 8°C (36° to 46°F).

Do Not Freeze or Shake. Keep in Carton to Protect from Light.

Rx Only

Manufactured by Amgen Inc.

Thousand Oaks, CA 91320-1799

U.S. License No. 1080

1 - Single Use Neulasta Prefilled Syringe  
1 - Sterile On-body Injector for Neulasta

NDC 55513-192-01

AMGEN

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Example for Marqibo:

### PRINCIPAL DISPLAY PANEL - 103 mg/mL Vial Label

NDC 20536-324-01

Rx only

### Sphingomyelin-Cholesterol Liposome Injection 103 mg/mL

for use only in the preparation of Marqibo®

Single Use Vial – Discard Unused Portion

See package insert for preparation instructions

Mfg. for: Talon Therapeutics, Inc., South San Francisco, CA 94080

Mfg. by: Cangene Corporation, Winnipeg, MB Canada R3T 5Y3



NDC 20536-324-01

Rx only

**Sphingomyelin-Cholesterol Liposome Injection**  
**103 mg/mL**

for use only in the preparation of **Marqibo®**

Single Use Vial – Discard Unused Portion

See package insert for preparation instructions

Mfg. for: Talon Therapeutics, Inc., South San Francisco, CA 94080

Mfg. by: Cangene Corporation, Winnipeg, MB Canada R3T 5Y3

DATA  
MATRIX  
FPO

Lot  
Exp.  
Imprint area